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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,551	01/08/2001	Casey D. Morrow	UAI-004CPDV2CN	6750

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,551

Applicant(s)

MORROW ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a continuation of 09/376,184, filed August 17, 1999, now abandoned, which is a continuation of 08/987,867, filed December 9, 1997, now patent number 6,063,384, which is a continuation of 08/389,459, filed February 15, 1995, now patent number 5,817,512, which is a continuation of 08/087,009, filed July 1, 1993, now abandoned.

As indicated in the action mailed July 7, 2004, this application has been withdrawn from issuance, and prosecution has been reopened. A new grounds of rejection is being made with references not previously made of record.

Claims 49-63 are pending and currently under examination as they are drawn to a method of expressing a foreign gene in a cell both *in vivo* and *ex vivo*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49, 53, 55, 57, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi *et al.*

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Choi *et al.* teach a poliovirus genome that has at least a portion of the P1 gene deleted and replaced with the non-polio sequence encoding the viral gag, pol and env proteins from HIV-1. Choi *et al.* demonstrate that when the vector (see for example figure 1) is transfected into HeLa cells it can express the heterologous sequences of HIV-1 (see figure 3 for example).

Claims 49, 50, 53, 55, 57 and 61 are rejected under 35 U.S.C. 102(a) as being anticipated by Percy *et al.*

Percy *et al.* teach a polio virus vector in which P1 is disrupted and non-polio gene is inserted (see figure 1 for example). Percy *et al.* insert the CAT reporter gene into the vector and demonstrate that through complementation of required sequences deleted from the poliovirus vector present in a helper cell encapsulated particles can be formed (see summary in abstract). Further, it was demonstrated that the particles were intact and subsequently capable of infecting cells in culture as demonstrated by plaque formation (see Table 1 and summary on page 5045, bridging first and second columns).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber *et al.* (US Patent 5,662,896), Percy *et al.* and Choi *et al.*

Barber *et al.* teach methods and compositions for cancer immunotherapy where a combination of antigens and/or cytokines are expressed using vectors delivered to a patient (see for example summary of invention, section starting in column 6, line 16, and claims 1-4). Barber *et al.* teach that retroviral vectors can be used in various methodology to deliver to and express in the therapeutic sequence in a patient (column 10, line 30-67). Included in the vectors specifically contemplated is the use of polioviral vectors (column 10, lines 44-47). However, Barber *et al.* does not describe the specific methodology or vectors known in the art for introducing a recombinant poliovirus vector to a cell. Percy *et al.* and Choi *et al.* each teach recombinant polioviral vectors that express non-polio sequences when administered to a cell, and detailed requirements of the vectors for propagation, delivery and expression of the heterologous sequence in a cell. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the specific and detailed methodology of providing a recombinant poliovirus vector capable of expressing non-polio viral proteins as taught by Percy *et al.* and Choi *et al.* in the general methods of delivery and treatment taught by Barber *et al.* One having ordinary skill in the art would have been motivated to use a polioviral vector because of the specific teaching of Barber *et al.* to do so. There would have been a reasonable expectation of success for the ability of polioviral vectors to be delivered and used in the methods of Barber *et al.* given his specific suggestion to use these vectors and citations of

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relevant prior art of the use of such vectors and in light of the results of Percy *et al.* and Choi *et al.* demonstrating the ability of recombinant polioviral vectors to express a variety of non-polio sequences in a variety of different cell types.

Conclusion

No claim is allowed.

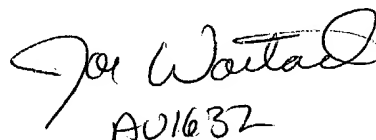
It was indicated previously that a method to stimulate an immune response to a protein produced by the vector has been allowed in US Patent 6,063,384 ('384) which is similar to the present method which is drawn more generally to providing expression of a protein in a cell. However, in the case of '384 the rejection was overcome by providing arguments that the immune response was unexpected in view of the cited references. In this case, there is a reasonable expectation that a protein will be expressed as evidenced by both Percy *et al.* and Choi *et al.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


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